K101892

AUG 27 2010

510(k) Summary of Safety and Effectiveness

In accordance with the requirements of the Safe Medical Device Act, HEINE Optotechnik GmbH & Co. KG herewith submits a Summary of Safety and Effectiveness.

Submitter Information:

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Date Prepared: July 02, 2010

Device(s) Identification:

Device Trade Name: HEINE Gamma G7®; G5®; GP®; GST®; XXL LF®
Common Name: Non-Automated Sphygmomanometers

Classification of the device:

Device Classification Name: Blood Pressure Cuff
Product Code: DXQ
Device Classification No.: Part 870.1120
Panel: Cardiovascular
Regulatory Status: Class II

Predicate devices:

1.
Device Trade Name: Riester Precisa N
Applicant: RUDOLF RIESTER GMBH & CO. KG
510(k) No.: K972379

2.
Device Trade Name: Riester Risan
Applicant: RUDOLF RIESTER GMBH & CO. KG
510(k) No.: K002954

3.
Device Trade Name: Riester Big Ben
Applicant: RUDOLF RIESTER GMBH & CO. KG
510(k) No.: K972301

4.
Device Trade Name: Riester Sanaphon
Applicant: RUDOLF RIESTER GMBH & CO. KG
510(k) No.: K972378

The HEINE GAMMA aneroid sphygmomanometers are considered substantial equivalent to the Riester Precisa N (K972379), Riester Risan (K002954), Riester Big Ben (K972301), and Riester Sanaphon (K972378).
There is no significant difference in intended use or technology.

Device Description:
The HEINE Gamma aneroid sphygmomanometers are non-invasive blood-pressure measurement devices to measure systolic and diastolic blood pressure in adults and pediatric patients. The HEINE Gamma sphygmomanometers consist of a large insufflation bulb, a gauge with a large diameter scale, a valve, and a single tube or twin tube cuff with Velcro fastener.

The HEINE Gamma sphygmomanometers come in five models; G5, G7, GP, GST, and XXL LF. The models comprise either a push-button valve or a spin valve. The HEINE Gamma GST comprises an integrated stethoscope for self measurement. The HEINE Gamma XXL LF is a wall-, desk-, or rail-mounted devices and is available with a wheeled stand. HEINE Gamma G5, G7, GP, and XXL LF will be available in five cuff sizes; child small, child, adult small, adult, and thigh. The HEINE Gamma GST comes with an adult cuff.

The HEINE Gamma aneroid sphygmomanometers are intended for use in a wide variety of settings. This includes hospital departments, medical practices, and nursing homes, as well as home health care.

Intended Use:
The HEINE Gamma Sphygmomanometers are used for non-automated blood pressure measurement by professional and lay users. The devices are non-sterile and are intended as multi-patient reusable devices. The HEINE Gamma Sphygmomanometers are available in infant through adult sizes.

Summary of Non-Clinical Performance Testing:
Bench Testing was conducted to demonstrate Safety and Effectiveness by conformance to the *ANSI/AAMI SP9-1994* standard for non-automated Sphygmomanometers, as referenced in the FDA Guidance *Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1.*

Conclusion:
HEINE Optotechnik believes that the HEINE Gamma aneroid sphygmomanometers are substantially equivalent to the currently legally marketed devices. They do not introduce new indications for use, have the same technological characteristics and do not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Heine Optotechnik,GmbH & Co., Kg
c/o Mr. Thomas Weber
PROSYSTEM AG
Beim Strohhause 27
Hamburg, GERMANY 20097

AUG 27 2010

Re: K101892
Trade/Device Name: Heine GAMMA® Sphygmomanometers
Regulatory Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: II (two)
Product Code: 74 DXQ
Dated: July 5, 2010
Received: July 7, 2010

Dear Mr. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101892

Indications for Use

510(k) number (if known):

Device Name: HEINE GAMMA® Sphygmomanometers

Indications For Use: HEINE GAMMA aneroid sphygmomanometers are exclusively designed for measuring blood pressure at the upper arm or thigh on healthy skin.

Prescription Use_____ AND/OR Over-The-Counter Use__X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101892

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